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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/842,776 | 04/27/2001 | Christian Reiter | 41735 | 4137 |
| 22204 | 7590 | 09/08/2005 | EXAMINER | |
| NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128 | | | NAVARRO, ALBERT MARK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/842,776 | REITER ET AL. | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 54-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 54-91 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2004 has been entered.

Claim Rejections - 35 USC § 112

1. The rejection of claims 54-91 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants are asserting that the invention provides a method of reliably detecting an infection of an acid-resistant microorganism, particularly *Helicobacter pylori* in the stool by using at least two monoclonal antibodies or fragments or derivatives thereof. Applicants further assert that the recited epitopes show "a structure after intestinal passage that corresponds to a native structure or a structure which a mammal produces antibodies against after being infected. Applicants further assert that in a preferred

embodiment the two epitopes are of a urease and a heat shock protein, preferably HSP 60.

Applicants arguments have been fully considered but are not found to be fully persuasive.

The claims are directed to methods for detecting an infection of an acid-resistant microorganism in stool with a monoclonal antibody or "fragment or derivative thereof."

First, Applicants assert that the invention provides a method of reliably detecting an infection of an acid-resistant microorganism, particularly Helicobacter pylori in the stool by using at least two monoclonal antibodies or fragments or derivatives thereof. However, Applicants are again directed back to their own claims, which recite methods of detection with monoclonal antibodies or "fragments or derivatives thereof." It is these derivatives which bind to unspecified antigens of unspecified structure which are being questioned. Again, the structure of the epitope is not set forth. Without guidance as to what the structure of the immunogen looks like, one of skill in the art would be hard pressed to determine which antibody derivatives are capable of specifically binding an antigen of undisclosed structure. As set forth in Rudinger et al "Peptide Hormones" edited by Parsons et al, University Park Press, June 1976, pp 1-7, especially page 6, teach that "the significance of particular amino acids and sequences for different aspects of biological activity cannot be determined a priori but must be determined from case to case by painstaking experimental study."

Second, Applicants assert that the recited epitopes show "a structure after intestinal passage that corresponds to a native structure or a structure which a mammal

Art Unit: 1645

produces antibodies against after being infected." However, Applicants are again reminded that the rejection is set forth due to the recitation of antibody derivatives. Since the structure of the epitope is not set forth by the claims, one of skill would be forced into excessive experimentation to identify antibody fragments and derivatives which are capable of "specifically binding" epitopes of unknown structure.

Finally, Applicants assert that in a preferred embodiment the two epitopes are of a urease and a heat shock protein, preferably HSP 60. However, the claims are still directed towards antibody derivatives. The structure and binding ability of these compounds cannot be determined by those of skill in the art, accordingly, one of skill in the art would be forced into excessive experimentation to practice the instantly claimed invention.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad of derivatives encompassed in the scope of the claims one skill in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 54-91 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The claims are directed to methods for detecting an infection of an acid resistant microorganism in the stool wherein the monoclonal antibody specifically binds an “epitope of the first antigen” and specifically binds “an epitope of a second antigen.”

Applicants are asserting that the claims require that the recited epitope show “a structure after intestinal passage that corresponds to a native structure” not any epitope.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that the recited epitope show “a structure after intestinal passage that corresponds to a native structure” not any epitope. However, Applicants are respectfully directed to the claim language which recites “**an epitope of an antigen.**” (Emphasis added). This is directly addressed by the teachings of Fox (US Patent Number 4,879,213), which sets forth that “short linear polypeptides often appear not to have the ability to mimic the required secondary and tertiary conformational structures to constitute appropriate immunogenic and antigenic determinants.” (See column 3). This is directly analogous to Applicants claim to an “epitope” of an antigen. An epitope is a short linear peptide obtained from a larger antigenic structure which has secondary and tertiary conformational structures. Furthermore, Applicants claims do not set forth of the structure of this epitope. Consequently, one of skill in the art would be forced into excessive experimentation to determine which epitope of unknown structure is capable of retaining a structure after intestinal passage similar enough to bind an antibody that also binds the native structure prior to intestinal passage.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 54-91 under 35 U.S.C. 112, second paragraph, as being indefinite vague and indefinite in the recitation of "derivative" is maintained.

Applicants are asserting that this phrase is not unclear, but rather well defined, and methods for obtaining derivatives are adequately disclosed in the specification.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants arguments are not found to be persuasive in view of the term "derivative." Derivative as defined by Dorlands Medical Dictionary 27th Edition, 1988 is a substance derived from another substance "either directly or by modification." The degree the substance can be modified and still remain under the scope of a derivative, simply cannot be determined by one of skill in the art.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

This is a continuation of applicant's earlier Application No. 09/842,776. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
August 25, 2005